the framework developed under paragraph (b) of this section to the extent feasible, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

(iii) The State receives CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(2) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) In requesting CMS approval, the State must include the following:

(i) The alternative quality rating system framework, including the performance measures and methodology to be used in generating plan ratings; and,

(ii) Documentation of the public comment process specified in paragraphs (c)(2)(i) and (ii) of this section, including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must document any policy revisions or modifications made in response to the comments and rationale for comments not accepted; and,

(iii) Other information specified by CMS to demonstrate compliance with paragraph (c) of this section.

(4) The Secretary, after consulting with States and other stakeholders, shall issue guidance which describes the criteria and process for determining if an alternative QRS system is substantially comparable to the Medicaid managed care quality rating system in paragraph (b) of this section.

(d) *Quality ratings.* Each year, the State must collect data from each MCO, PIHP, and PAHP with which it contracts and issue an annual quality rating for each MCO, PIHP, and PAHP based on the data collected, using the Medicaid managed care quality rating system adopted under this section.

(e) *Availability of information.* The State must prominently display the quality rating given by the State to each MCO, PIHP, or PAHP under paragraph (d) of this section on the Web site required under § 438.10(c)(3) in a manner that complies with the standards in § 438.10(d).

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020]

§ 438.340 Managed care State quality strategy.

(a) *General rule.* Each State contracting with an MCO, PIHP, or PAHP as defined in § 438.2 or with a PCCM entity as described in § 438.310(c)(2) must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP or PCCM entity.

(b) *Elements of the State quality strategy.* At a minimum, the State's quality strategy must include the following:

(1) The State-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by §§ 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires in accordance with § 438.236.

(2) The State's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2).

(3) A description of—

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2) with which the State contracts, including but not limited to, the performance measures reported in accordance with § 438.330(c). The State must identify which quality measures and performance outcomes the State will publish at least annually on the website required under § 438.10(c)(3); and,

(ii) The performance improvement projects to be implemented in accordance with § 438.330(d), including a description of any interventions the

State proposes to improve access, quality, or timeliness of care for beneficiaries enrolled in an MCO, PIHP, or PAHP.

(4) Arrangements for annual, external independent reviews, in accordance with § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)) contract.

(5) A description of the State's transition of care policy required under § 438.62(b)(3).

(6) The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. For purposes of this paragraph (b)(6), ''disability status'' means, at a minimum, whether the individual qualified for Medicaid on the basis of a disability. States must include in this plan the State's definition of disability status and how the State will make the determination that a Medicaid enrollee meets the standard including the data source(s) that the State will use to identify disability status.

(7) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(8) The mechanisms implemented by the State to comply with § 438.208(c)(1) (relating to the identification of persons who need long-term services and supports or persons with special health care needs).

(9) The information required under § 438.360(c) (relating to nonduplication of EQR activities).

(10) The State's definition of a ''significant change'' for the purposes of paragraph (c)(3)(ii) of this section.

(c) *Development, evaluation, and revision.* In drafting or revising its quality strategy, the State must:

(1) Make the strategy available for public comment before submitting the strategy to CMS for review, including:

(i) Obtaining input from the Medical Care Advisory Committee (established by § 431.12 of this chapter), beneficiaries, and other stakeholders.

(ii) If the State enrolls Indians in the MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2), consulting with Tribes in accordance with the State's Tribal consultation policy.

(2) Review and update the quality strategy as needed, but no less than once every 3 years.

(i) This review must include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years.

(ii) The State must make the results of the review available on the Web site required under § 438.10(c)(3).

(iii) Updates to the quality strategy must take into consideration the recommendations provided pursuant to § 438.364(a)(4).

(3) Submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback prior to adopting it in final.

(ii) A copy of the revised strategy whenever significant changes, as defined in the state's quality strategy per paragraph (b)(11) of this section, are made to the document, or whenever significant changes occur within the State's Medicaid program.

(d) *Availability.* The State must make the final quality strategy available on the Web site required under § 438.10(c)(3).

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020]

§ 438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs, or with PCCM entities (described in § 438.310(c)(2)) must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, PAHP or PCCM entity (described in § 438.310(c)(2)).

(b) The EQRO has sufficient information to use in performing the review.

(c) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358 or, if applicable, from a Medicare or private accreditation review as described in § 438.360.

(d) For each EQR-related activity, the information gathered for use in the EQR must include the elements described in § 438.364(a)(2)(i) through (iv).

(e) The information provided to the EQRO in accordance with paragraph (b) of this section is obtained through